

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Transmissible Spongiform Encephalopathies Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

*Name of Committee:* Transmissible Spongiform Encephalopathies Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on June 26, 2002, from 8 a.m. to 5:30 p.m.; and June 27, 2002, from 8:30 a.m. to 12 noon.

*Location:* Holiday Inn, The Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

*Contact Person:* William Freas or Sheila D. Langford, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12392. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* On June 26, 2002, the committee will discuss validation of procedures to prevent contamination and cross-contamination with transmissible spongiform encephalopathies agents of human tissue intended for transplantation. In the afternoon the committee will discuss the "FDA Draft Guidance on Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Human Cells, Tissues, and Cellular and Tissue-Based Products." On June 27, 2002, the committee will listen

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to updates on: (1) Implementation of blood donor deferrals for risk of vCJD; (2) recent reports of infectivity detected in blood of sheep experimentally infected with bovine spongiform encephalopathies and scrapie agents; and (3) recent reports of abnormal prion proteins and infectivity detected in muscles of experimentally infected mice.

*Procedure:* On June 26, 2002, from 8 a.m. to 2:15 p.m. and from 3 p.m. to 5:30 p.m.; and on June 27, 2002, from 8:30 a.m. to 12 noon, the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by June 19, 2002. Oral presentations from the public will be scheduled between approximately 12:15 p.m. and 1:15 p.m. on June 26, 2002; and between 10:30 a.m. and 11:30 a.m. on June 27, 2002. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 21, 2002, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

*Closed Committee Deliberations:* On June 26, 2002, from 2:15 p.m. to 3 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). This portion of the meeting will be closed to permit discussion of this material.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

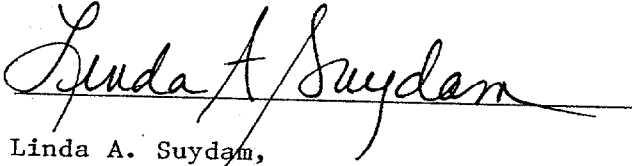
FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact William Freas or Sheila D. Langford at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: 5-23-02

May 23, 2002.



Linda A. Suydam,  
Senior Associate Commissioner for Communications and Constituent Relations.

~~SUPPLEMENTARY INFORMATION: ?????~~

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]



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